

Exhibit A



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VIA ECF

The Honorable Ron Clark
U.S. District Court for the Eastern District of Texas
300 Willow Street, Suite 221
Beaumont, TX 77701

Re: Mark A. Barry, MD v. Medtronic, Inc., No. 1:14-cv-00104-RC (Beaumont Div.)

Dear Judge Clark:

Pursuant to the Court's Scheduling Order (D.I. 46) and related discussions during the May 13, 2015 status conference, Defendant Medtronic, Inc. ("Medtronic") respectfully submits this letter brief detailing why the patents-in-suit are invalid under 35 U.S.C. § 102(b). Specifically, Dr. Mark Barry, the named inventor on each of the asserted patents, has repeatedly admitted in sworn statements, including the patents' specifications as well as verified interrogatory responses, that he performed *twenty-one* scoliosis surgeries that practiced the claimed inventions of the patents more than a year before filing them.

Faced with invalidation of his patents due to this admitted prior public use, on May 26, 2015, Dr. Barry materially amended his previously verified interrogatory responses, including an amendment that deleted prior sworn admissions that the prior art surgeries used the patented "invention" – without *any* explanation or support for such changes – in a last ditch effort to salvage his patents. That Dr. Barry and his counsel tried to rewrite history approximately one week before Medtronic's deadline to file this letter brief – and more than 9 months after Medtronic first raised this issue with Plaintiff – is particularly telling. And, other than these after-the-fact, self-serving, implausible and unverified statements,¹ there is not a single shred of documentary evidence suggesting that the surgeries were experimental in nature. The reason for this lack of any contemporaneous evidence is simple – there is none. Such attempts to create issues of fact by deleting and contradicting his own prior statements should be rejected, and warrant appropriate sanctions, in deciding summary judgment. *See S.W.S. Erectors, Inc. v. Infax, Inc.*, 72 F.3d 489, 495 (5th Cir. 1996) ("It is well settled that this court does not allow a party to defeat a motion for summary judgment using an affidavit that impeaches, without explanation, sworn testimony."); *see also Magnus Elecs., Inc. v. Masco Corp.*, 1986 WL 10061, at *13 (N.D. Ill. Sept. 5, 1986) ("Incomplete or false answers to written interrogatories justify an order under Rule 37 imposing sanctions."); *Dotson v. Bravo*, 202 F.R.D. 559, 567 (N.D. Ill. 2001) ("Knowingly incomplete and misleading answers to written interrogatories constitutes perjury, as well as, fraud."), *aff'd*, 321 F.3d 663 (7th Cir. 2003).

¹ Dr. Barry did not verify his amended responses as required by Rule 33. *See Johnson v. Derhaag Motor Sports, Inc.*, 2014 WL 5817004, at *8 (D. Minn. Nov. 10, 2014) ("plaintiff's responses to interrogatories are invalid on procedural grounds, regardless of the substance of the answers given" for failure to sign under oath).

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** STRATEGIC ALLIANCE

I. Dr. Barry's Patents are Invalid Under 35 U.S.C. § 102(b) Because He Performed 21 Surgeries Using the Alleged Inventions More than A Year before Filing

A. 35 U.S.C. § 102(b) is an absolute bar to patentability

An inventor loses the right to obtain a patent on an invention if he “uses it publicly more than a year before filing” and the invention is “ready for patenting.” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379, 1381 (Fed. Cir. 2005) (citing 35 U.S.C. § 102(b)). This absolute bar to patentability is based upon the public policies of: (i) “discouraging removal of inventions from the public domain which the public justifiably comes to believe are freely available”; (ii) “favoring prompt and widespread disclosure of inventions;” and (iii) “prohibiting an extension of the period for exploiting the invention.” *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860 (Fed. Cir. 1985).

B. Dr. Barry admits that he performed surgeries using the alleged inventions more than one year before filing for patent protection

In the patents themselves, Dr. Barry clearly and unequivocally admits that he performed surgeries using the alleged patented inventions before he filed the patents:

FIG. 6 is a three frame x-ray view showing “before and after” views of a scoliosis patient who was treated in an investigational procedure *using the system and method of the present invention*.

(*See* Exs. 1-3, '358 patent at 4:38-43; '072 patent at 4:41-46; '121 patent at 4:44-49, respectively) (emphasis added). The patents-in-suit tout the unparalleled success in treating this patient with the patented inventions:

As shown in FIG. 6, investigative practice of *the present method achieves efficacy never before seen* in the orthopaedic field. The “before picture” is the left hand image of FIG. 6 and the two remaining images are sagittal and dorsal views of the corrected spinal column.

(*Id.*, '358 patent at 5:60-64; '072 patent at 6:7-11; '121 patent at 6:10-14) (emphasis added). Although not disclosed to the U.S. Patent Office during prosecution of the patents, Plaintiff recently confirmed that the surgery that resulted in the x-rays depicted in Figure 6 was performed more than one year before the asserted patents' earliest claimed priority date of December 30, 2004: “[T]he x-rays depicted in Figure 6 were taken on or about July 10, 2003, and the surgery was performed June 10, 2003.” (Mar. 12, 2015 email from J. Reed to R. Pettus). Thus, this surgery, which Dr. Barry admits in his patents used “the system and method of the present invention,” creates an absolute bar to patentability under § 102(b).

Moreover, as part of his LR 3-2(a) mandatory disclosures, Dr. Barry produced an abstract that he submitted for publication in February 2004 (“the 2004 Abstract”), which demonstrates that he had performed 21 surgeries – including the June 10, 2003 surgery which resulted in Figure 6 – using the claimed inventions before filing for patent protection and that the “92% correction” seen in these 21 surgeries was “predictable and reproducible.” (*See* Ex. 9).² In fact, Dr. Barry admitted in his original interrogatory responses (ex. 4, p. 16) that the

² For the later-filed '072 and '121 patents, the 2004 Abstract itself is invalidating prior art under § 102(b).

surgeries detailed in the 2004 Abstract were done “using his invention.” Again recognizing that this sworn interrogatory response would be fatal to his case against Medtronic, Dr. Barry recently amended his response by *deleting the words “using his invention”*:

“Subject to and without waiver of the aforementioned objections, Dr. Barry gave a presentation on his to-date investigational steps relating to a three-dimensional deformity correction technique and associated interim apparatus ~~using his invention~~ at the IMAST conference in July of 2004.”

(Cf. Exs. 5 vs. 6 - the latter being a redline created by Medtronic to show the changes to the responses). Similarly, the amended interrogatory responses also attempt to ***explain away as “mistake[s]” the contemporaneous sworn admissions in the patents*** that the surgical procedure of Figure 6 used “the system and method of the present invention” to achieve “never before seen” efficacy, by stating:

This Figure [6] is mistakenly described in the patents, and instead represents the end result that would be achieved through the use of what ultimately became my invention ... [but which] was mistakenly and inadvertently described as using my invention, when, in fact it only portrayed results achievable through use of my invention. The photos depict results that, though never achieved before this particular depicted surgery ... showed only that the ideas I had were worth pursuing at the time The ***invention to realize such results in practicable, repeatable and safe manner*** for others was not realized at the time of these photos. Any methods or systems in development were not practicable before late 2004.

(*Id.* at 6; emphasis added). This belated attempt by Dr. Barry and his patent prosecution (and trial) counsel, David Henry, to recast the “methods and systems” used in these 21 prior surgeries as not “practicable” or “repeatable” is completely belied by the clear patent record and Dr. Barry’s other contemporaneous written descriptions in his 2004 Abstract that he published well “before late 2004” telling the world that the surgical methods and associated “linked multiple derotation” instrumentation resulted in “[e]xcellent 92% correction” that “is predictable and reproducible.” (Ex. 9). Even if Plaintiff’s contorted explanation (of last week) is accepted as true, the patents would still be invalid and unenforceable. By admitting that the Figure 6 surgery was 102(b) prior art, and that the results achieved by its method and system were the same as (and key to the development of) the alleged invention, they necessarily admit that allegedly later-developed inventions of the patents did not produce the improved and “never before seen” results that Dr. Barry and Mr. Henry touted, under oath, as a basis for patentability in their application to the Patent Office. (Ex. 1, 5:60-64). Such specious efforts to create issues of fact without evidentiary support in order to avoid summary judgment should be rejected³ and warrant sanctions.⁴ *Reese v. AT & T Mobility II, LLC*, 2014

³ Dr. Barry’s admissions in the patents’ specifications were sworn to be true and correct by him at the time of their submission to the Patent Office, and neither he nor his counsel should be permitted to selectively rewrite them through contradictory, unsworn, interrogatory responses many years later. See *In re Cygnus Telecomms. Tech., LLC, Patent Litig.*, 481 F.Supp.2d 1029, 1050 (N.D. Cal. 2007) (discrediting inventor declaration contradicting prior sworn statements to the PTO because “[p]atent applications are ex parte proceedings which have substantial effect upon the rights of the public, and as such, [the inventor and his counsel] had a duty to ensure filings were accurate”), *aff’d*, 536 F.3d 1343 (Fed. Cir. 2008).

WL 1873046, at *4 (C.D. Cal. May 9, 2014) (amended interrogatory response served days after court granted leave to file summary judgment discredited as “self-serving, suspect, and insufficient to raise a genuine issue of material fact”); *see also Hughes v. Novi Am., Inc.*, 724 F.2d 122, 125 (Fed. Cir. 1984) (sanctions affirmed for “false answers to interrogatories”).

II. The Argument That All 21 Surgeries Constitute “Experimental Use” Must Fail

Prior to his amended interrogatory responses, Dr. Barry did not dispute that the 21 surgeries were prior uses of the claimed inventions. Rather, he told this Court that “the referenced 21 surgeries fall under the experimental-use exception” to § 102(b).⁵ (*See* Dkt. 44 at 2). The law is clear, however, that experimental use is a very narrow exception to the 102(b) absolute bar to patentability: “To establish that an otherwise public use does not run afoul of section 102(b), it must be shown that the activity was ‘substantially for purposes of experiment.’” *Netscape Comm’ns Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002); *see also Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317, 1327 (Fed. Cir. 2009). In the instant case, Dr. Barry cannot dispute the public nature of the surgery represented by the x-rays in Figure 6 or any of the other 21 surgeries described in the 2004 Abstract. In his sworn interrogatory responses, Dr. Barry acknowledges that each and every one of the 21 surgeries were observed by “a surgical assistant, an anesthesiologist, a nurse, a scrub technician, an x-ray technician, a spinal cord monitoring neurophysiologist, and the sales and support representative from [a] medical device company” and that “no separate written confidentiality agreements were formed with or between any of the aforementioned persons.” (*See* Exs. 4-5, Resp. to Interrogatory No. 2 at 9-10).⁶ Further, Dr. Barry admits that he published to the world the details of the surgical technique and instrumentation used on the “series of 21 consecutive patients” as well as the “[e]xcellent” results achieved in the 2004 Abstract and the patents in suit. (Ex. 9). All of these admitted facts stand in direct

⁴ The fact that Dr. Barry and Mr. Henry are now recanting sworn statements to the PTO as false, while both knew or should have known that the 21 prior surgeries were material prior art, but never disclosed their dates and details to the PTO, is clear evidence of inequitable conduct and presents grounds for an exceptional case. *See Deep Sky Software, Inc. v. Southwest Airlines Co.*, 10-cv-1234-CAB (S.D. Cal., June 1, 2015) (“If a plaintiff knows that its patent would not have issued but for the intentional omission of material information during prosecution of the patent [i.e., prior art that he considered key to the development and implementation of his claimed invention], then the plaintiff knows that the patent is invalid and acts deceitfully in suing for its infringement. Such circumstances would support a finding of an exceptional case.”) (Opinion attached, Ex. 12).

While we intend to depose both Dr. Barry and Mr. Henry in the coming weeks, Medtronic fully expects to amend its Answer to add a charge of inequitable conduct, and to move to disqualify Mr. Henry and his firm. Clearly recognizing the conflict, last week Plaintiff voluntarily offered to self-disqualify Mr. Henry and institute a Chinese wall. But, that is too little too late, and the entire firm should be disqualified where, as here, counsel worked closely together for over a year in the litigation with full knowledge of this issue, and Dr. Barry has also retained the Fish & Richardson law firm to represent him.

⁵ Dr. Barry’s assertion that “in light of the PTAB’s denials of Medtronic’s petitions for Inter Partes Review, any argument of invalidity by Medtronic is far from clear or dispositive” is misplaced because issues of prior public use cannot be raised in an IPR petition. *See* 35 U.S.C. § 311(b) (permissible grounds are “only on the basis of prior art consisting of patents or printed publications”).

⁶ Dr. Barry now acknowledges that “instrument modifications” were “done at a local precision machine shop” without mention of any secrecy agreements or payments associated with such commercial activities. (*Id.*) He also produces no informed consent agreements from any of the 21 patients upon whom he performed the allegedly “experimental” surgical procedures, casting further doubt on his argument that such surgeries were in fact experimental in nature.

contradiction to Dr. Barry's recently amended interrogatory response stating that each of the 21 consecutive prior public uses "was a private operation, not observed or made public at the time." (Ex. 5, at 4). Finally, Dr. Barry admitted to having been fully compensated for performing each and every one of those surgeries "in a manner consistent with standard surgical billing by submitting the proper CPT codes to Medicaid or the applicable private insurance company." (*Id.* at 10). These admissions and his failure to produce any records referring to the surgeries as "experimental" further demonstrate that none of these prior public use surgeries were in fact experimental. As held in an analogous case:

The objective evidence in this case cuts heavily against experimental use. Sinskey charged his usual surgical fee of \$1,900 for each of the eight operations and IOLAB charged its standard \$250 price for the lenses. He did not inform the patients that they were being treated with a "new" or "experimental" lens, nor did he obtain any kind of secrecy agreement from the patients or surgical staff. None of the documents provided by IOLAB or Sinskey ever referred to the Model 103J as "experimental" or the subject of tests. Apparently routine medical records of these implantations were kept, but Sinskey does not refer to them specifically, and they were not put before the district court. If they contained any indication that the implantations were part of an experimental or test program, rather than routine operations, it is fair to assume Sinskey would have offered them.

Sinskey v. Pharmacia Ophthalmics, Inc., 982 F.2d 494, 499 (Fed. Cir. 1992); *see also Small v. Nobel Biocare USA, LLC*, 2013 WL 3972459, *11-*13 (S.D. N.Y. 2013). In short, other than the unverified Amended Interrogatory Responses, Dr. Barry provides absolutely no evidence (contemporaneous or otherwise) supporting his new argument that the 21 surgeries were experimental and, thus, cannot satisfy and establish the experimental use exception as a matter of law or fact. *Id.* ("Post-hoc affidavit testimony alone, years after the events described and purporting to show an inventor's subjective experimental intent, will never satisfy the burden of establishing experimental use in a case like this where there is no contemporaneous evidence of experimental purpose and the objective evidence is to the contrary.")⁷

For all of the foregoing reasons, Medtronic respectfully requests that summary judgment of invalidity under 35 U.S.C. § 102(b) be granted in its favor, or that it be permitted to present such a motion to the Court.

Respectfully submitted,

/s/ Scott J. Bornstein

Scott J. Bornstein, Esq.

⁷ Dr. Barry may try to excuse his lack of contemporaneous evidence as being due to the loss of his records prior to filing this suit during computer system conversions and the like. However, the fact remains that, despite knowing of the accused Medtronic product since 2005, Dr. Barry waited until 2014 to file this suit. (Ex. 4, Interrogatory No. 4, p. 12, "Dr. Barry first became aware of a posterior derotation system offered by Medtronic sometime in 2005."). Thus, even assuming the truth of any of his excuses, such spoliation or unavailability of material evidence should weigh against him. *See Netscape*, 295 F.3d at 1322 (rejecting experimental use defense where patentee "presented no objective evidence that he maintained any records of testing the [invention]").